PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/01

A1

(11) International Publication Number: WO 00/67666

(43) International Publication Date: 16 November 2000 (16.11.00)

(21) International Application Number: PCT/IE99/00036

(22) International Filing Date: 7 May 1999 (07.05.99)

(71) Applicant (*for all designated States except US*): SALVIAC LIMITED [IE/IE]; 39–40 Upper Mount Street, Dublin 2 (IE).

(72) Inventors; and
(75) Inventors/Applicants (*for US only*): VALE, David [IE/IE]; 26 The Stiles Road, Clontarf, Dublin 3 (IE). BRADY, Eamon [IE/IE]; 12 Karol Avenue, Elphin, County Roscommon (IE).

(74) Agents: O'BRIEN, John, A. et al.; John A O'Brien & Associates, 3rd floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).

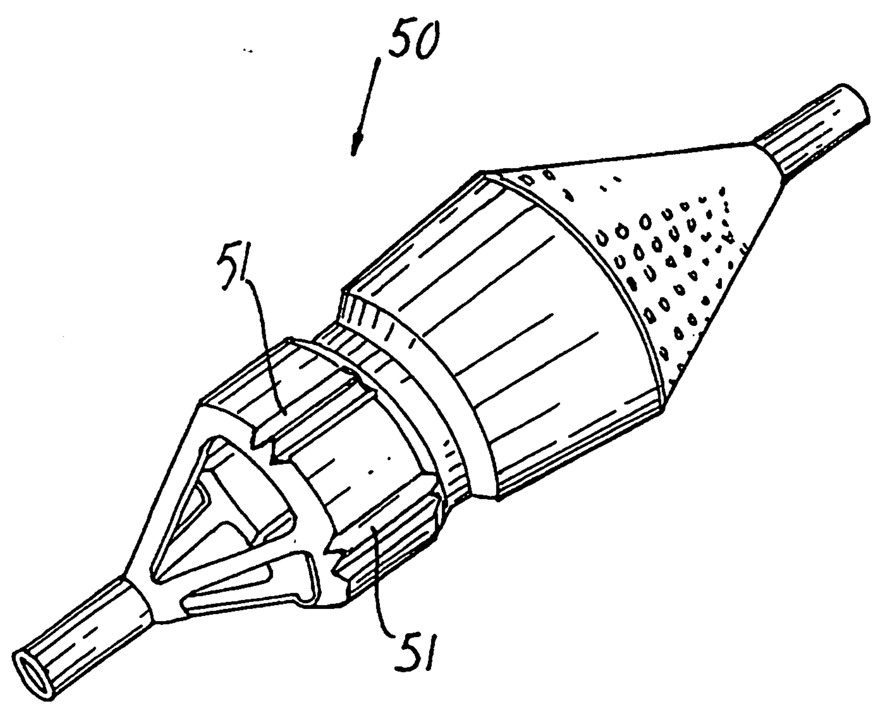
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published**
*With international search report.*

(54) Title: IMPROVED FILTER ELEMENT FOR EMBOLIC PROTECTION DEVICE

(57) Abstract

A collapsible filter element (2, 10, 20, 50, 40) for an embolic protection device comprises a filter body which has a relatively stiff portion (3) and a relatively soft portion (5) for engaging a vessel wall. The proximal and/or distal ends (3, 4) may be the stiff portion to provide enhanced web strength. To cater for a range of vessel sizes the filter body may have corrugations or ribs (46, 51).



# "IMPROVED FILTER ELEMENT FOR EMBOLIC PROTECTION DEVICE"

This invention relates to a filter element for a transcatheter embolic protection device.

## Introduction

The invention is particularly concerned with filter elements for transcatheter embolic protection devices of the type described in our previously filed PCT Patent Application No. PCT/IE98/00093 the contents of which are incorporated herein by reference. One type of such embolic filter essentially comprises a filter body mounted on an associated collapsible support frame which can be collapsed against the guide wire by means of a catheter for deployment of the filter through a patient's vascular system. Upon retraction of the catheter the support frame and filter body expand outwardly from the guidewire across a blood vessel within which the filter is positioned to filter blood flowing through the blood vessel.

A practical problem that arises with filter elements of such embolic protection devices is that they should be able to accommodate blood vessels of different diameter as it would be impractical to manufacture a large range of filters each of different size to accommodate all possible diameters of blood vessel. To provide flexibility and accommodate a range of vessel sizes with a given size of filter a relatively soft and elastic filter body material can be used. It is, however, important that the filter when deployed maintains its shape during use and to prevent distortion or collapsing of the filter body in use. Because of this and also the need for adequate strength in the body material, the walls of the filter body tend to be relatively thick. This presents a problem in that the filter then has a relatively large crossing profile when in the collapsed deployment position, which is undesirable.

The present invention is directed towards overcoming these problems.

Statements of Invention

According to the invention there is provided a collapsible filter element comprising:

a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

an inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

an outlet end of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

wherein the filter body has a first relatively stiff portion and a second relatively soft portion for engaging a circumferential vessel wall.

Ideally the first portion has a larger wall thickness than the wall thickness of the second portion.

In a particularly preferred embodiment of the invention the filter body is of composite construction.

In one embodiment of the invention, the filter body comprises a proximal body section and a distal body section, one of which forms said stiff first portion and the other forming the soft second portion.

Preferably the proximal body section forms the soft second portion.

In a further embodiment, the filter body comprises a proximal body section and a distal body section interconnected by an intermediate body section, one or both of the proximal body section and the intermediate body section forming the soft second portion, the distal body section forming the stiff first portion.

In another embodiment the proximal body section has a ribbed outer surface.

Preferably a plurality of spaced-apart longitudinal ribs are provided on the proximal section.

In another embodiment the proximal body section includes corrugations.

Brief Description of the Drawings

The invention will be more clearly understood by the following description of some of the embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 is partially sectioned elevational view an embolic protection device;

Fig. 2 is a schematic sectional elevational view of the embolic protection device of Fig. 1;

Fig. 3 is a detail sectional view of portion of the device of Fig. 1;

Fig. 4 is a longitudinal cross sectional view of the device of Fig. 1;

Fig. 5 is a cross sectional view of a distal end of the device of Fig. 1;

Fig. 6 is a view on the line A-A in Fig. 5;

Fig. 7 is a perspective view of a filter body of the device of Figs. 1 to 6;

Fig. 8 is a side elevational view of the filter body of Fig. 7;

Fig. 9 is a view on a proximal end of the filter body;

Fig. 10 is a perspective view of a support frame of the device of Figs. 1 to 6;

Fig. 11 is a side elevational view of the support frame;

Fig. 12 is a perspective view illustrating the manufacture of the support frame;

Fig. 13 is a view of the support frame and filter element assembly;

Fig. 14 is a longitudinal cross sectional view of a filter body according to the invention;

Fig. 15 is a longitudinal cross sectional view of another filter body according to the invention;

Fig. 16 is a longitudinal cross sectional view of a further filter body according to the invention;

Fig. 17 is a schematic perspective view of a filter element according to another aspect of the invention; and

Fig. 18 is another schematic perspective view of a filter element of the invention.

Detailed Description

Referring to Figs. 1 to 13 there is illustrated an embolic protection device as described in our co-pending Application PCT/IE98/00093 indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

The filter 105 comprises a filter body 110 mounted over a collapsible support frame 111. The filter body 110 is mounted to the sleeve 104 at each end, the body 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the body 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the body 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

The filter body 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material

to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olive surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter body 110. If the filter is too large for a vessel, the body may crease and this groove 125 ensures any crease does not propagate along the filter.

Enlarged openings are provided at a proximal end of the filter body 110 to allow ingress of blood and embolic material into an interior of the body 110.

In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand expanding the filter body 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the filter body 110. The blood will pass through the net wall, however, the openings or pores in the net are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the filter body against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter body.

Further, the catheter engages the proximal end of the filter body first thus closing the filter body inlet and preventing escape of embolic material from the filter body as the filter body is being collapsed.

The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with diisocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621, 065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also suitable.

The filter material may also be a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9, 1998, the entire contents of which are incorporated herein by reference. The filter material may be manufactured from a block and cut into a desired shape. However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations involve processes such as mechanical machining operations, laser machining or chemical machining.

The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body polymeric material. The rod may be of an acrylic material which is dissolved by a suitable solvent such as acetone.

The polymeric body thus formed is machined to the shape illustrated in Figs. 1 to 13. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, and outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

The inlet holes 117 are provided in the proximal portion 210 which allow the blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple point contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that line apposition of the filter body to the vessel wall is achieved. It is expected that other geometrics of stiffening means will achieve a similar result.

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the axial length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 215 is preferably at least 0.5 and ideally greater than 1.0.

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

The support frame 111 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to cause the filter body 110 to open.

The support frame may be formed as illustrated in Fig. 12 by machining slots in a tube 291 of shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, the distal collar 293 is slidably moveable along the tubular sleeve 104 which in turn is slidably mounted on the guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

To load the filter the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to pull off the filter freeing the support arms 290 to expand and the filter body apposes the vessel wall.

For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus entrapping the embolic load. As the filter continues to be pulled back the filter

body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

Referring to Fig. 14 there is illustrated a filter element comprising a filter 2 according to the invention. In this case, the filter body 2 has a proximal section 3 and a distal section 4 interconnected by an intermediate section 5. Both the proximal section 3 and the distal section 4 are made from a relatively stiff grade of polyurethane material which enables a low wall thickness to be achieved, thus advantageously minimising the bulk of the filter when it is in a collapsed position so that it has a low crossing profile while at the same time providing adequate strength. The intermediate section 5 is made from a soft elastic grade of polyurethane having good shape memory characteristics which will help the filter maintain the desired expanded shape during use of the filter. This soft portion also allows one filter size to accommodate a range of vessel sizes conforming closely to the vessel wall to prevent blood and embolic material bypassing the filter.

In the filter body 14 illustrated in Fig. 14 the body is of generally uniform thickness in cross section. However, to achieve any desired variation in the properties of the filter body the thickness may be variable such as in the filter body 10 illustrated in Fig. 15.

Referring to Fig. 16, any required structural properties may also be provided by manufacturing the filter body 20, at least partially from a laminate construction of the same or different materials. In the illustration of Fig. 16 the distal portion 4 and part of the intermediate portion 5 are of twin layer 21, 22 construction. The layers 21, 22 may be of the same of different materials. Keying means, either mechanical or chemical may be provided between the layers. There may be multiple layers and a different layer structure may be provided at any desired locations of the filter body to achieve required properties.

Referring now to Fig. 17 there is shown another filter element according to the invention, indicated generally by the reference 40. The filter element 40 has a filter body 42 of generally similar construction to the filter element described previously with reference to Figs. 1 to 16, the body having a proximal section 43 and a distal section 44 interconnected by an intermediate section 45. In this case, the distal section 44 is of a relatively hard polyurethane material whilst the proximal section 43 and intermediate section 45 are of a softer grade polyurethane material. A number of longitudinal ribs 46 are provided around a circumference of the proximal section 43. Advantageously, this construction facilitates close engagement of an outer circumference of the proximal section 43 against a vessel wall to minimise the risk of embolic material bypassing the filter element 40. An internal spring frame, as described above, urges the proximal section 43 outwardly so that it expands against and closely conforms with the wall of the blood vessel in which the filter element 40 is mounted in use.

Conveniently, the corrugations or ribs 46 allow the proximal section 43 of the filter element 40 to accommodate a wider range of vessel sizes whilst maintaining good contact between the outer circumference of the proximal section 43 and the vessel wall and providing improved web strength and filter body integrity.

Referring to Fig. 18 there is illustrated another filter element 50 according to the invention. In this case corrugations 51 are provided for improved apposition and web strength.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

1 A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:

a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

an inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

an outlet end of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

wherein the filter body has a first relatively stiff portion and a second relatively soft portion for engaging a circumferential vessel wall.

2. A filter element as claimed in claim 1 wherein the first portion has a larger wall thickness than the wall thickness of the second portion.

3. A filter element as claimed in claim 1 or 2 wherein the filter body is of composite construction.

4. A filter element as claimed in any preceding claim wherein the filter body comprises a proximal body section and a distal body section, one of which forms said stiff first portion and the other forming the soft second portion.

5. A filter as claimed in claim 4 wherein the proximal body section forms the soft second portion.

6. A filter element as claimed in any of claims 1 to 4 wherein the filter body comprises a proximal body section and a distal body section interconnected by an intermediate body section, one or both of the proximal body section and the intermediate body section forming the soft second portion, the distal body section forming the stiff first portion.

7. A filter element as claimed in any of claims 4 to 6 wherein the proximal body section has a ribbed outer surface.

8. A filter element as claimed in any of claims 4 to 7 wherein a plurality of spaced-apart longitudinal ribs are provided on the proximal section.

9. A filter as claimed in any of claims 4 to 8 wherein the proximal body section includes corrugations.

10. A filter element substantially as hereinbefore described with reference to the accompanying drawings.

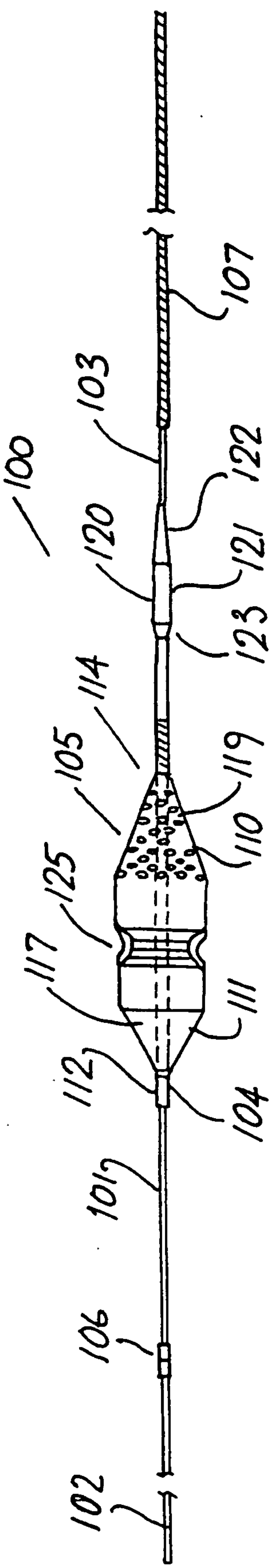

100
103
107
122
120
121
123
114
105
119
110
125
117
111
112
104
101
106
102

Fig.1

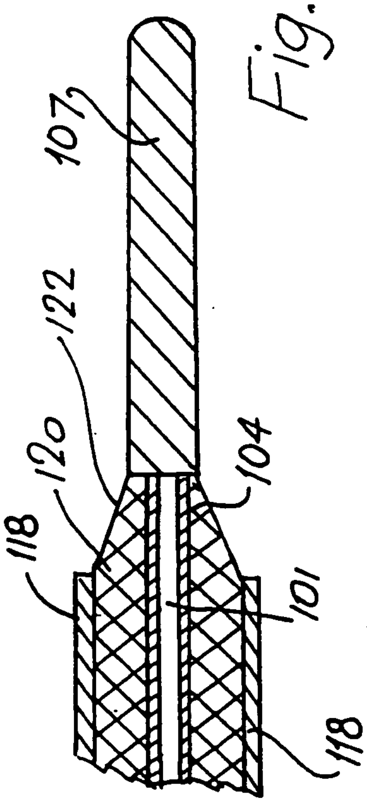

107
122
120
118
104
101
118

Fig. 3

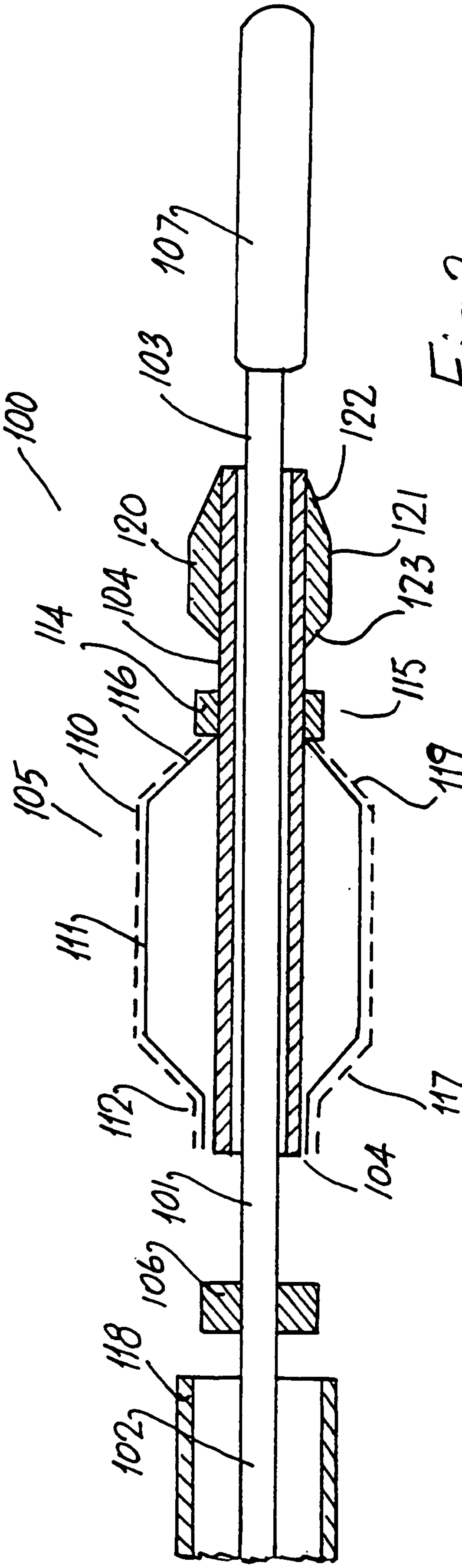

107
103
100
122
120
121
123
104
114
116
110
115
105
119
111
112
117
104
101
106
118
102

Fig. 2

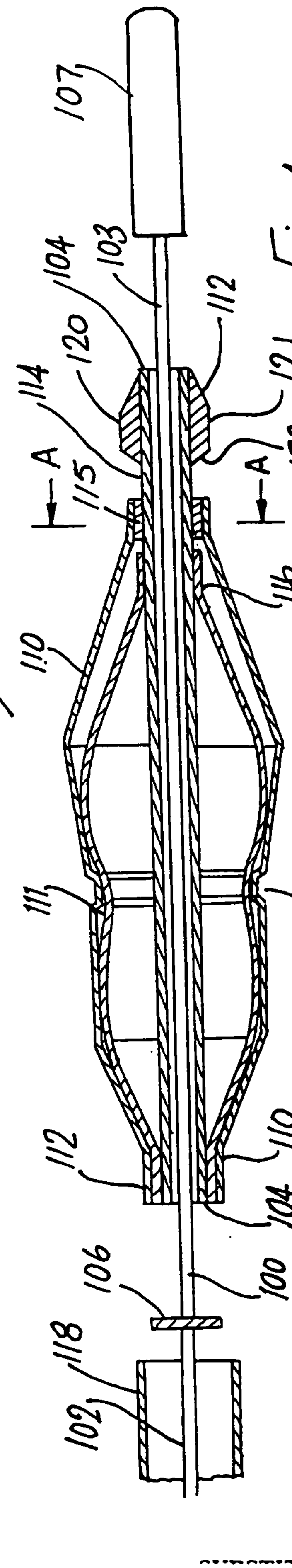



Fig.4

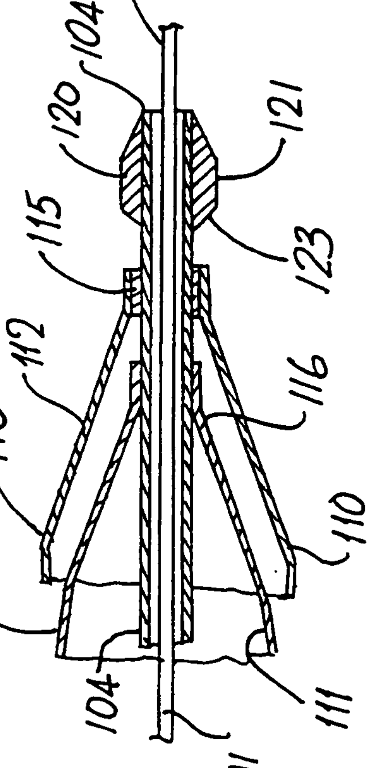



Fig.5

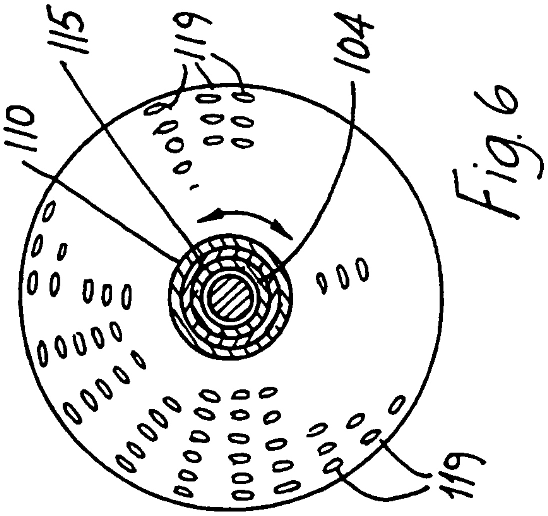



Fig.6

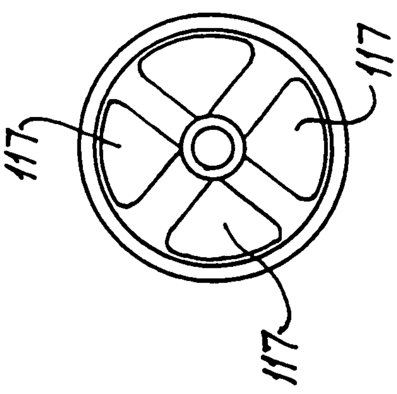



Fig.9

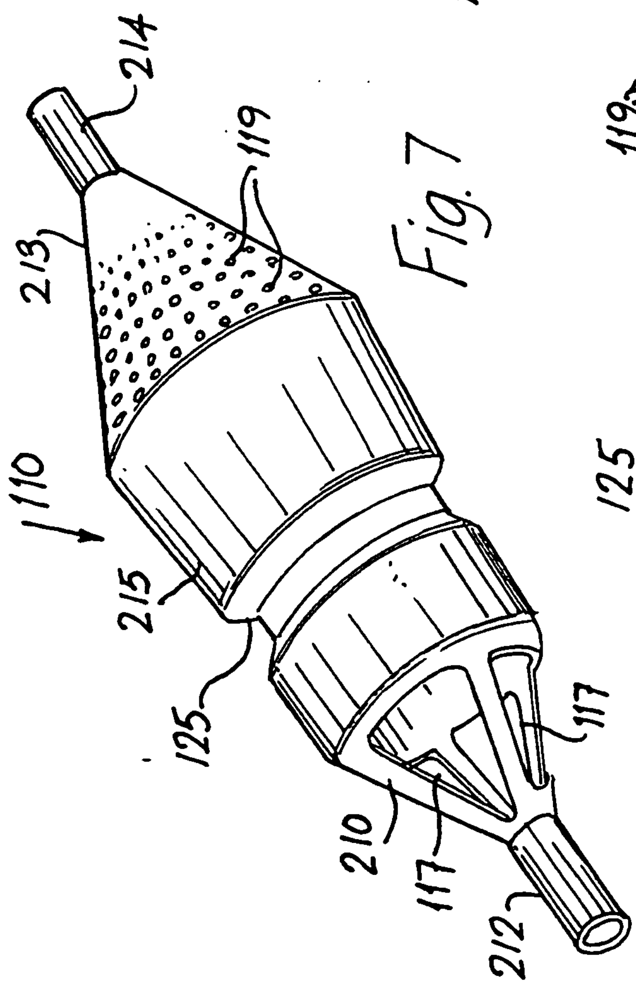



Fig. 7

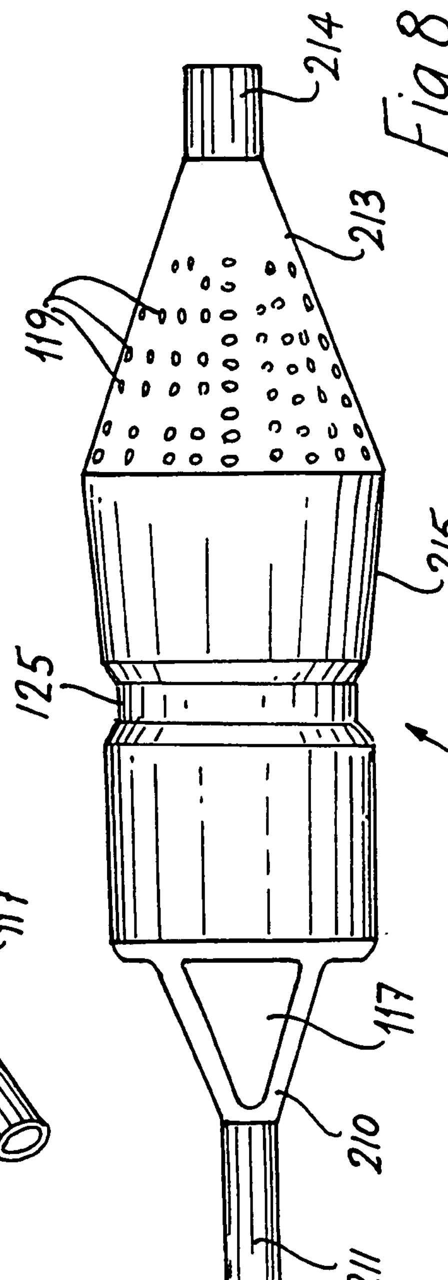



Fig.8

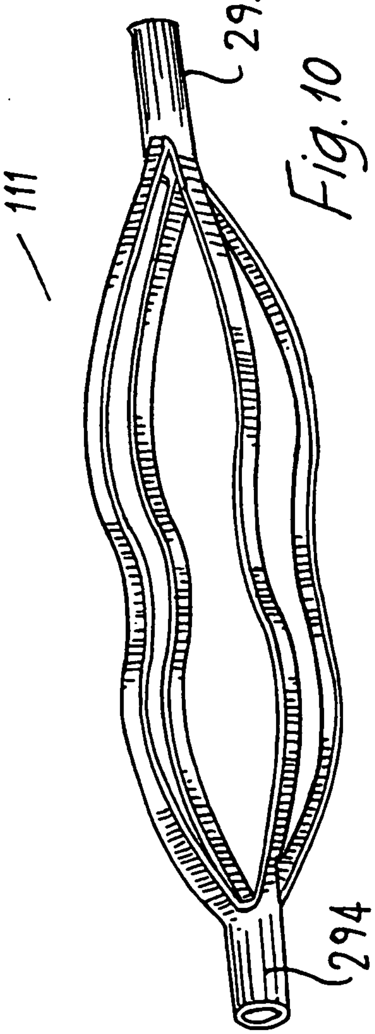



Fig. 10

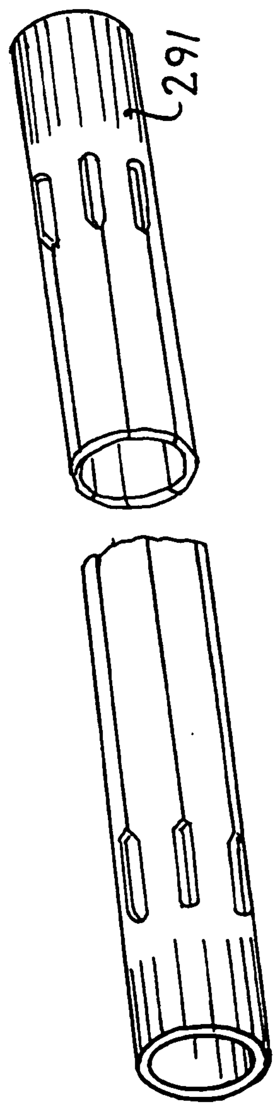



Fig.12

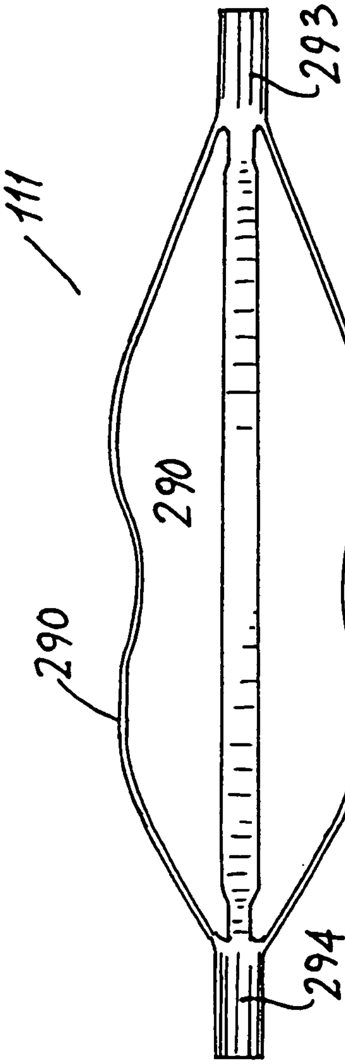



Fig.11

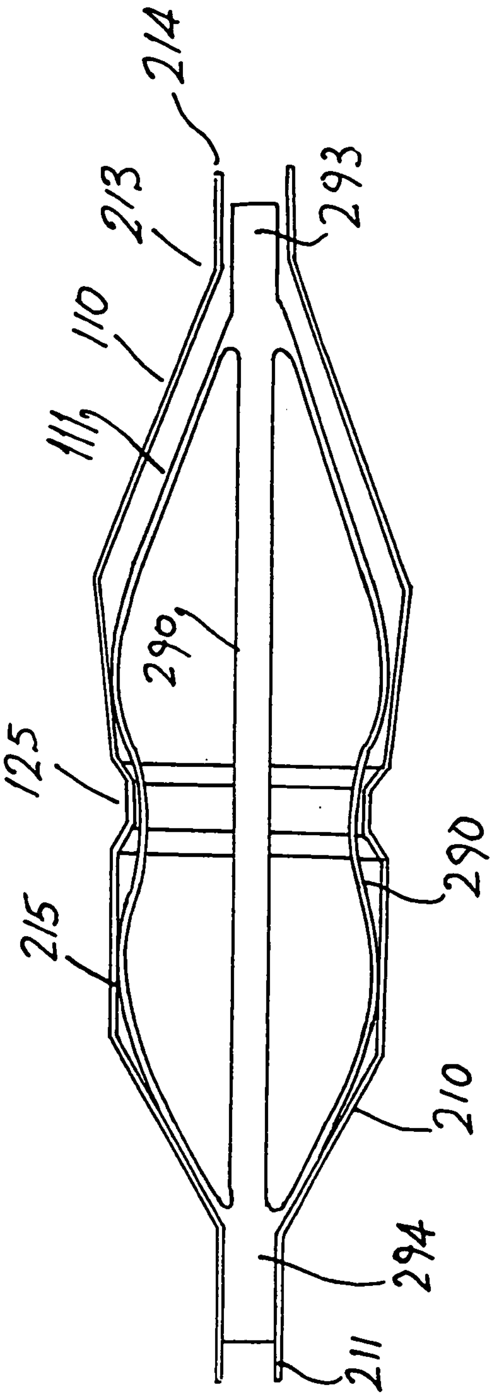



Fig. 13

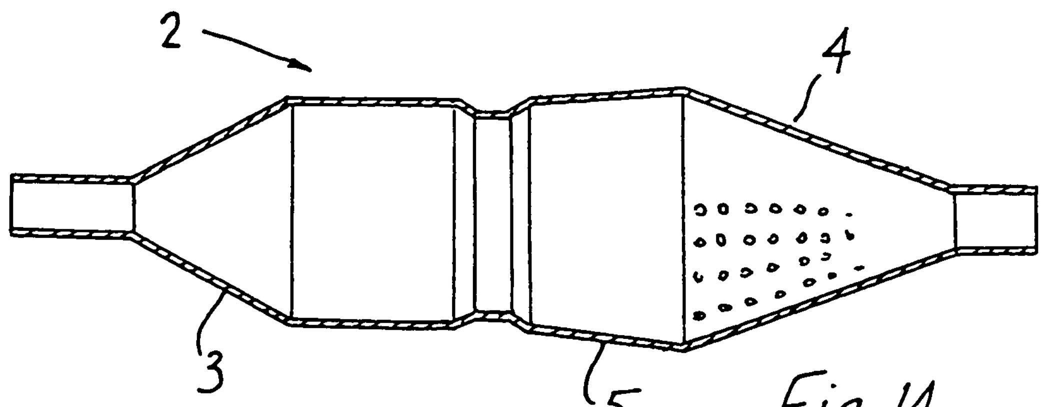



Fig. 14

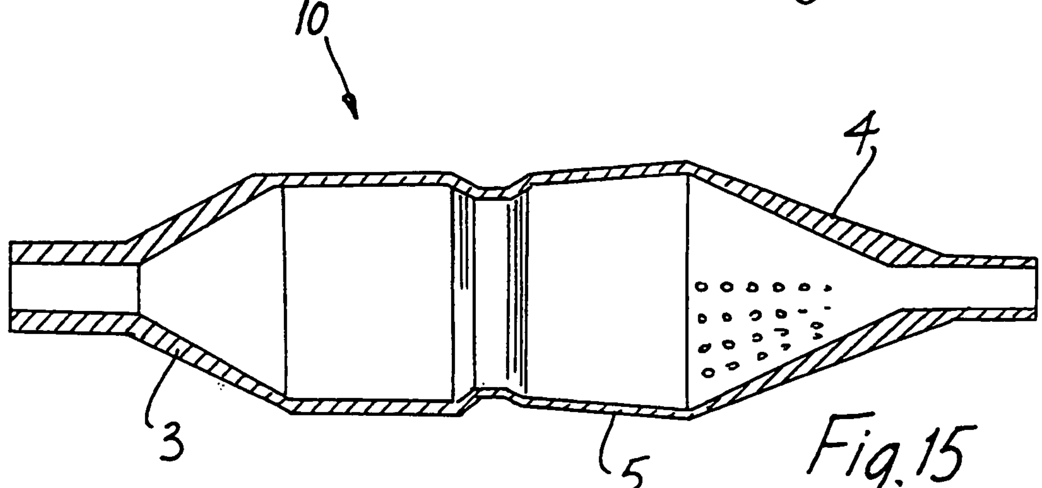



Fig. 15

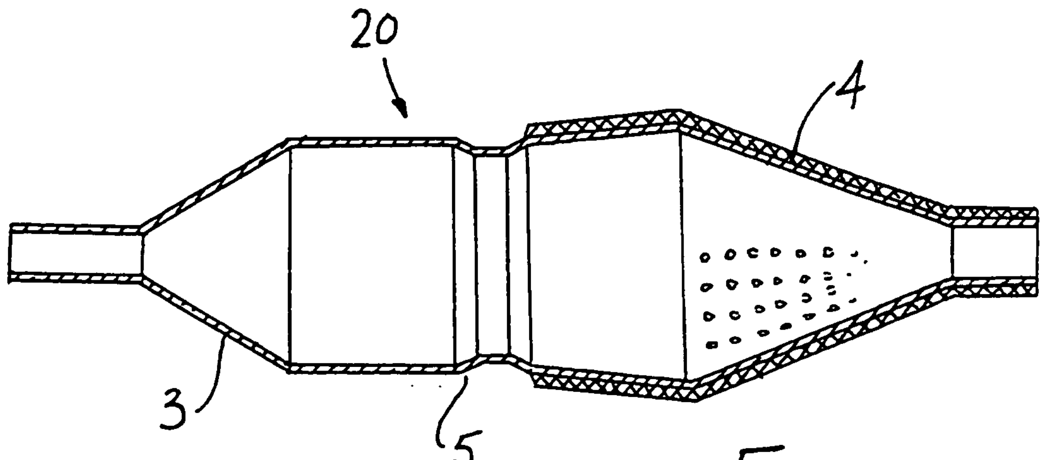



Fig. 16

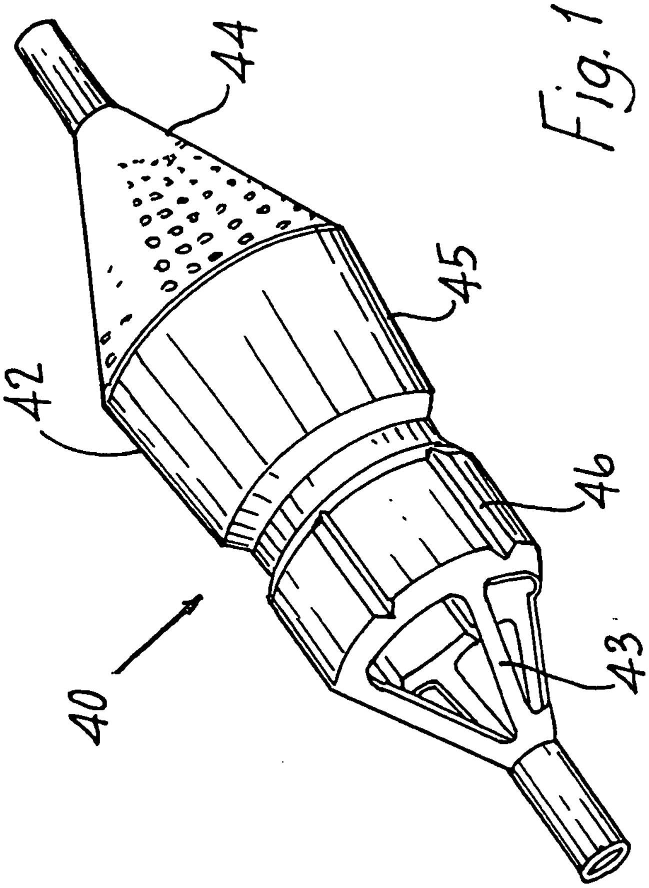



Fig. 17

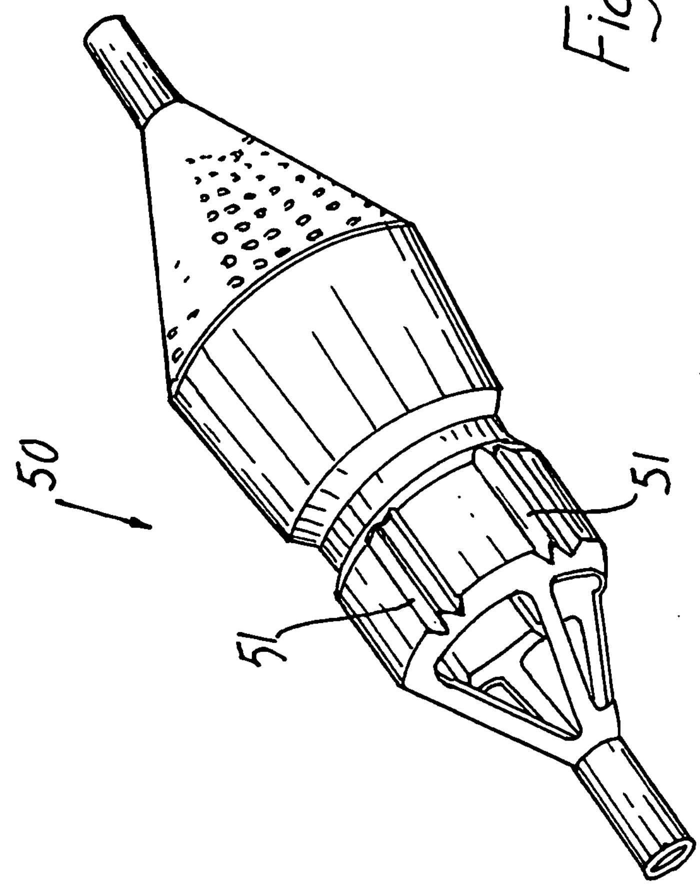



Fig.18

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 99/00036

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 98 51237 A (GERTLER ET AL) 19 November 1998 (1998-11-19) the whole document<br>----- | 1-3 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 5 January 2000 | 13/01/2000 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Smith, C |

1

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 99/00036

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 10
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Rule 6.2(a) PCT

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/IE 99/00036

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 9851237 A | 19-11-1998 | US 5954745 A | 21-09-1999 |